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68904 U.S. PTO 05/14/97

11105 U.S. PTO 08/855933 05/14/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 1998-028-25 DIV

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir: This is a request for filing a

☐ Continuation

application under 37 C.F.R. §1.60,

☒ Divisional

of copending prior application Serial No. 08/510,046, filed on May 31, 1995
of MATTHEW T. SCHOLZ, ROBERT A. SCHERRER, NELDA M. MARECKI, YEN-LANE CHEN, JOAN K. BARKHAUS (Inventors) for
BIOADHESIVE COMPOSITION AND PATCH (title of invention)

1. "Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or Declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application Serial No. 08/510,046, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon."

2. ☐ A verified statement to establish Small Entity status under 37 CFR 1.9 and 1.27

   ☐ is enclosed

   ☐ was filed in prior application Serial No. _____ and such status is still proper and desired (37 CFR 1.28(a)).

3. ☒ The filing fee is calculated below:

CLAIMS AS FILED, LESS ANY CLAIMS CANCELLED BY PRELIMINARY AMENDMENT AND/OR AMENDMENT BELOW

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS	20 -20 =	-	X $ 22 =	$ -
	INDEPENDENT	3 - 3 =	-	X $ 80 =	$ -
	MULTIPLE DEPENDENT CLAIMS			+ $260 =	$ -
			BASIC FEE		$ 770.00
			TOTAL OF ABOVE CALCULATIONS=		$ 770.00
	Reduction by 50% for filing by Small Entity				$ -
				TOTAL	$ 770.00

4. ☒ The Commissioner is hereby authorized to charge any fees which may be required for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Account No. 15-0030. A duplicate copy of this sheet is enclosed.

5. ☒ A check in the amount of $ 770.00 is enclosed.

6. ☒ Cancel Claims (See Preliminary Amendment).

7. ☒ Amend the specification by inserting before the first line the sentence:
--This is a ___ Continuation, XX Division, of application Serial No. 08/510,046 filed on May 31, 1995, pending, which is a XX Division of application Serial No. 07/842,222, filed on February 26, 1992, now abandoned, which is a XX Continuation of application Serial No. 07/607,863, filed on November 1, 1990, now abandoned, which is a XX Continuation-In-Part of application Serial No. 07/486,554, filed on February 27, 1990, now abandoned, which is a XX Continuation-In-Part of application Serial No. 07/431,664, filed on November 3, 1989, now abandoned.--

8. ☐ Drawing(s) are enclosed.

9. ☒ Priority of the following application(s) is claimed under 35 U.S.C. 120:

Application No.	Filing Date	Status
08/510,046	May 31, 1995	Pending
07/842,222	February 26, 1992	Abandoned
07/607,863	November 1, 1990	Abandoned
07/486,554	February 27, 1990	Abandoned
07/431,664	November 3, 1989	Abandoned

10. ☒ The prior application is assigned to: Minnesota Mining & Manufacturing, Co., P.O. Box 33427, St. Paul, Minnesota 551330-3427 .

11. ☒ The Power of Attorney in the prior application is to one or more of the following: Norman F. Oblon, Reg. No. 24,618; Marvin J. Spivak, Reg. No. 24,913; C. Irvin McClelland, Reg. No. 21,124, Gregory J. Maier, Reg. No. 25,599; Arthur I. Neustadt, Reg. No. 24,854; Richard D. Kelly, Reg. No. 27,757; James D. Hamilton, Reg. No. 28,421; Eckhard H. Kuesters, Reg. No. 28,870; Robert T. Pous, Reg. No. 29,099; Charles L. Gholz, Reg. No. 26,395; Vincent J. Sunderdick, Reg. No. 29,004; William E. Beaumont, Reg. No. 30,996; Steven B. Kelber, Reg. No. 30,073; Robert F. Gnuse, Reg. No. 27,295; Jean-Paul Lavalleye, Reg. No. 31,451; Stephen G. Baxter, Reg. No. 32,884; Martin M. Zoltick, Reg. No. 35,745; Robert W. Hahl, Reg. No. 33,893; Richard L. Treanor, Reg. No. 36,379; Steven P. Weihrouch, Reg. No. 32,829; John T. Goolkasian, Reg. No. 26,142; Marc R. Labgold, Reg. No. 34,651; William J. Healey, Reg. No. 36,160; Richard L. Chinn, Reg. No. 34,305; Steven E. Lipman, Reg. No. 30,011; Carl E. Schlier, Reg. No. 34,426; James J. Kulbaski, Reg. No. 34,648; Catherine B. Richardson, Reg. No. 39,007; Richard A. Neifeld, Reg. No. 35,299; J. Derek Mason, Reg. No. 35,270; and Jacques M. Dulin, Reg. No. 24,067, all of OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C., Fourth Floor, 1755 Jefferson Davis Highway, Arlington, Virginia 22202.

a. ☐ The power appears in the original papers of the prior application.

b. ☒ Since the power does not appear in the original papers, a copy of the powers (2) in the prior application is enclosed.

c. ☐ Recognize as Associate Attorney and address all future communication to:

12. ☒ Preliminary Amendment is enclosed.

13. ☒ Also enclosed: White Advance Serial No. Card;
Copy: Oath, Power of Attorney, and Petition, (executed, 4 pages)

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Charles L. Gholz
Attorney of Record
Registration No. 26,395

Alton D. Rollins
Registration No. 34,083

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1755 Jefferson Davis Highway
Arlington, Virginia 22202
(703) 413-3000
(703) 413-2220 (fax)

1998-028-25DIV

IN RE APPLICATION OF :

MATTHEW T. SCHOLZ, :GROUP ART UNIT: 1502
ROBERT A. SCHERRER, : (anticipated)
NELDA M. MARECKI :
YEN-LANE CHEN AND :
JOAN K. BARKHAUS :

SERIAL NO: Divisional of :EXAMINER: P. KULKOSKY
08/510,046 (anticipated)

FILED: Herewith :

FOR: BIOADHESIVE COMPOSITION
AND PATCH

REQUEST FOR EXPEDITED PROSECUTION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The examiner is respectfully reminded that 37 CFR 1.607(b) provides in relevant part that:

> When an applicant seeks an interference with a patent, examination of the application... shall be conducted with special dispatch within the Patent and Trademark Office.

Respectfully submitted,

Alton D. Rollins

Charles L. Gholz
Registration No. 26,395
Alton D. Rollins
Registration No. 34,083
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1998-028-25 DIV

IN RE APPLICATION OF :

MATTHEW T. SCHOLZ, : GROUP ART UNIT: 1502
ROBERT A. SCHERRER, : (anticipated)
NELDA M. MARECKI :
YEN-LANE CHEN AND :
JOAN K. BARKHAUS :

divisional of :
SERIAL NO: 08/510,046 : EXAMINER: P. KULKOSKY
(anticipated)
FILED: Herewith :

FOR: BIOADHESIVE COMPOSITION
AND PATCH

37 CFR 1.607 REQUEST FOR AN
INTERFERENCE WITH A PATENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I. 37 CFR 1.607(a)(1)

The patent is U.S. patent No. 5,516,523 issued May 14, 1996 and naming Sonia J. Heiber, Charles D. Ebert, and Sirish C. Dave as inventors. The assignee at issue was TheraTech, Inc. of Salt Lake City, Utah.

II. 37 CFR 1.607(a)(2)

Applicants propose the following count, which is in the format approved by the Commissioner in Orikasa v. Oonishi, 10 USPQ2d 1999, 2003 (Comm'r 1990), and Davis v. Uke, 27 USPQ2d 1180, 1188 (Comm'r 1993):

Claim 1 in the Heiber et al. patent

OR

Claims 125, 132, or 139 in the Scholz et al. patent application.

An extra copy of the proposed count is submitted herewith for the examiner's use in filling out the form PTO-850. In addition, as explained in section IX of this request, a proposed form PTO-850 is submitted herewith for the examiner's convenience.

III. 37 CFR 1.607(a)(3)

All 24 claims in the Heiber et al. patent correspond to the proposed count. Indeed, the proposed count includes all of the independent claims in that patent.

IV. 37 CFR 1.607(a)(4)

Claims 125-144 presented in the 37 CFR 1.607(a)(4) amendment submitted herewith correspond to the proposed count. Indeed, the proposed count includes all of the independent claims in that group of claims.

While dependent claims 126-131, 133-138, and 140-144 do not correspond exactly to the proposed count, the applicants do not currently argue that any of those claims is drawn to a separate patentable invention within the meaning of 37 CFR 1.601(n).

V. 37 CFR 1.607(a)(5)

The terms of the application claims identified as corresponding to the proposed count and not previously in the

application can be applied to the disclosure of the application as follows:

Terms of the Claims	Application to the Disclosure of the Application
125. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to the oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
enhancer/	Page 14 lines 14-31.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
an opposing surface in contact with and adhering to an overlying inert layer,	Page 4 lines 3-5
said inner layer containing an effective amount of a bile salt enhancer,	Page 14 lines 14-30.
from about 29 to 80% by weight of a hydrophilic polymer,	Page 3 lines 21-23. (100 parts of hydrophilic resin to 20-250 parts of hydrophobic resin.)
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-

	21) are macromolecular drugs.
126. A method according to claim 125 wherein said bile salt enhancer is selected from the group consisting of sodium glycocholate, sodium taurocholate, and sodium tauro-24, 25-dihydrofusidate.	Page 14 lines 14-31.
127. A method according to claim 126 wherein said macromolecular drug is a member selected from the group consisting of polysaccharides, polypeptides, and proteins.	Page 14 lines 19-21; page 13 lines 3-6; insulin (page 13 line 5); and heparin (page 13 lines 10 and 19), a polysaccharide.
128. A method according to claim 127, wherein said hydrophilic polymer is a member selected from the group consisting of acrylic acid polymers, maleic acid polymers, itaconic acid polymers, citraconic acid polymers, methacrylic acid polymers;	Page 5 line 10 - page 12 line 8. Applicants' preferred hydrophilic polymer, Carbopol® 934 is well recognized as being a hydrophilic polymer. See Kirk-Othmer, Encyclopedia of Chemical Technology, Vol. 20 pp. 216-219. (John Wiley & Sons, 1982)(Attachment A).
copolymers of a member selected from the group consisting of acrylic acid and methacrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates;	Page 5 lines 10-23
and acrylic acid polymers cross-linked with a polyalkenyl ether selected	Page 5 line 24 - page 6 line 8. line 8.

from the group consisting of an allyl ether of sucrose and an allyl ether of pentaerythritol.	
129. A method according to claim 128 wherein the macromolecular drug is a polysaccharide.	Page 13 lines 19-21. Heparin is a macromolecular polysaccharide. See claims 8 and 9 of the '523 patent.
130. A method according to claim 129 wherein the polysaccharide is heparin.	Page 13 lines 19-21.
131. A method according to claim 128 in the form of a film patch wherein said inert layer is a polymer which is nonadhesive to mucosal tissues and is substantially impermeable to the bile salt enhancer or the drug.	Page 18 lines 9-34.
132. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/ enhancer/ polymer/	Page 3 lines 24-25. Page 14 lines 14-31. Page 3 lines 14-20.
layer having one surface adapted to contact	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.

the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer	
said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer,	Page 14 lines 14-30.
about 29 to 80% by weight of a hydrophilic polymer, and	Page 3 lines 21-23 (100 parts hydrophilic polymer to 20-250 parts hydrophobic polymer).
an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21.
133. A method according to claim 132 wherein the bile salt enhancer is sodium taurocholate.	Page 14 lines 14-21.
134. A method according to claim 133 wherein said macromolecular drug is a member selected from the group consisting of polysaccharides, polypeptides, and proteins.	Page 14 lines 19-21; page 13 lines 3-6; and insulin and heparin.
135. A method according to claim 134 wherein said hydrophilic polymer is a member selected from the group consisting of acrylic acid polymers, methacrylic acid polymers,	Page 5 line 10 - page 12 line 8. Applicants' preferred hydrophilic polymer, Carbopol® 934 is well recognized as a hydrophilic polymer. See Attachment A.

copolymers of acrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,	
methacrylic acid copolymers with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,	Page 5 lines 17-22.
and polymers of acrylic acid cross-linked with a polyalkenyl polyether.	Page 5 lines 24-34
136. A method according to claim 135 wherein the macromolecular drug is a polysaccharide.	Page 13 lines 19-21.
137. A method according to claim 136 wherein the polysaccharide is heparin.	Page 13 lines 19-21.
138. A method according to claim 135 in the form of a film patch wherein said inert layer is a polymer which is nonadhesive to mucosal tissues and is substantially impermeable to the bile salt enhancer or drug.	Page 18 lines 9-34.
139. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.

an inner drug/	Page 3 lines 24-25.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer,	Page 3 line 25 - page 4 lines 6 and 27-28.
said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer	Page 3 lines 21-23.
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
140. A method according to claim 139 wherein the macromolecular drug is a member selected from the group consisting of polysaccharides, peptides, and proteins.	Page 14 lines 19-21; page 13 lines 3-6; page 13 line 5 (insulin); and page 13 lines 10 and 19 (heparin).
141. A method according to claim 140 wherein said hydrophilic polymer is a member selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic acid with a member selected from the group consisting of methyl vinyl ether and lower alkyl methacrylates,	Page 5 line 10 - page 12 line 8.

copolymers of methacrylic acid with a member selected from the group consisting of methyl vinyl ether and alkyl methacrylates,	
and polymers of acrylic acid cross-linked with a polyalkenyl polyether.	
142. A method according to claim 141 wherein the macromolecular drug is a polysaccharide.	Page 13 lines 10 and 19 (heparin).
143. A method according to claim 142 wherein the polysaccaride is heparin.	Page 13 lines 10 and 19.
144. A method according to claim 139 wherein the macromolecular drug is heparin.and	Page 13 lines 10 and 19.
the hydrophilic polymer is a linear polyacrylic acid resin cross-linked with a member selected from the group consisting of an allyl ether of sucrose and an allyl ether of pentaerythritol.	Page 5 line 24 - page 6 line 8.

VI. 37 CFR 1.607(a)(6)

37 CFR 1.607(a)(6) is irrelevant since this request and the accompanying 37 CFR 1.607(a)(4) amendment are being

submitted prior to one year from the date on which the Heibert et al. patent was granted.

VII. REQUEST FOR THE BENEFIT OF THE FILING DATE OF APPLICANTS' PRIORITY APPLICATIONS

Applicants claim priority under 35 USC 120 based upon application SN 08/510,046 filed on May 31, 1995, 07/842,222, filed on February 26, 1992, 07/607,863 filed on November 01, 1990, 07/486,554 filed on February 27, 1990, and 07/431,664 filed on November 03, 1989. Applicants are entitled to the benefit of the filing dates of their earlier applications for interference purposes if the count reads on at least one adequately disclosed embodiment in the earlier application.[1] Assuming that the examiner recommends to the board applicants' proposed count, applicants clearly meet that standard. That this is so is demonstrated in the following table, which reads the terms of the count on their earlier applications.

Terms of the Count	Application of the Terms of the Count to the Disclosure of the 510,046 Application
A method of mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising an inner drug/	Page 4 lines 34-37 and page 5 lines 3-6. Page 3 lines 24-25.

[1] Weil v. Fritz, 572 F.2d 856, 865-66 n. 16, 196 USPQ 600, 608 n. 16 (CCPA 1978).

enhancer/	Page 14 lines 14-31.
polymer/	Page 3 lines 14-31.
layer having one surface in contact with and adhering to the mucosal tissue of the oral cavity and an opposing surface in contact with and adhering to an overlying inert layer	Page 3 line 25 - page 4 lines 6, 27, and 28.
said inner layer containing from about two to sixty percent by weight of a bile salt enhancer,	Page 14 lines 14-30.
five to sixty five percent by weight of a hydrophilic polymer and	Page 3 lines 21-23 (100 parts of hydrophilic polymer to 20-250 parts of hydrophobic polymer).
an effective amount of a macromolecular drug having a molecular weight of at least 500 daltons.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.

or

A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to the oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
enhancer/	Page 14 lines 14-31.
polymer	Page 3 lines 14-20

layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
an opposing surface in contact with and adhering to an overlying inert layer,	Page 4 lines 3-5
said inner layer containing an effective amount of bile salt enhancer,	Page 14 lines 14-30.
from about 29 to 80% by weight of a hydrophilic polymer	Page 3 lines 21-23. (100 parts of hydrophilic resin to 20-250 parts of hydrophobic resin).
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.
or	
A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/ enhancer/ polymer/	Page 3 lines 24-25. Page 14 lines 14-31. Page 3 lines 14-20.
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer	Page 3 line 25 - page 4 line 6 and page 4 lines 27-28.
	Page 14 lines 14-30

said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer,	
about 29 to 80% by weight of a hydrophilic polymer, and	Page 3 lines 21-23 (100 parts hydrophilic polymer to 20-250 parts hydrophobic polymer).
an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21.
139. A method for mucosally administering a macromolecular drug to the oral cavity comprising	Page 4 lines 13-22 and 34-37.
applying to an oral cavity mucosa a system comprising	Page 4 lines 34-37 and page 5 lines 3-6.
an inner drug/	Page 3 lines 24-25.
polymer	Page 3 lines 14-20
layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer,	Page 3 line 25 - page 4 lines 6 and 27-28.
said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer	Page 3 lines 21-23.
and an effective amount of a macromolecular drug.	Page 3 lines 24-25 and page 12 line 5 to page 13 line 21. Heparin (page 13 line 19); insulin (page 13 lines 5-6); and peptides and proteins (page 14 lines 19-21) are macromolecular drugs.

Since applicants' application is a straight continuation or division of the disclosures of application serial Nos. 08/510,046, 07/842,222, and 07/607,863, the disclosures of applicants' application is identical to the disclosures of those applications.

Application S.N. 431,664 discloses the hydrophilic polymer limitations of each of the alternative portions of the count at page 1 lines 2-28; the penetration enhancers at page 12 line 27 to page 13 line 7, particularly page 13 lines 2-5; and the macromolecular drug at page 10 line 20 to page 12 line 30 (including heparin, insulin, and human or animal growth hormones).

Example 13 at pages 26-27 of the 431,664 application describes patches containing 45% Carbopol® 910, a hydrophilic polymer, and 15% morphine sulfate, a macromolecular drug (molecular weight 669 daltons).

Application S.N. 486,554 carries forward the above disclosures from the 431,664 application at page 3 lines 8-34, page 5 line 4 to page 6 line 14, page 11 line 1 to page 12 line 33, page 13 lines 6-23, and Example 13 at pages 25-26.

VIII. 37 CFR 1.608

37 CFR 1.608 is irrelevant since the effective filing date of this application precedes the effective filing date of the Heider et al. patent.

IX. SUBMISSION OF PROPOSED FORM PTO-850

Submitted herewith for the convenience of the examiner is a proposed form PTO-850.

Respectfully submitted,

Charles L. Gholz
Registration No. 26,395
Alton D. Rollins
Registration No. 34,083
OBLON, SPIVAK, McCLELLAND,
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Fax: (703) 413-2220

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Form PTO-850

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INTERFERENCE-INITIAL MEMORANDUM

EXAMINERS INSTRUCTIONS - This form need not be typewritten. Complete the items below and forward to the Group Clerk with all files including those benefit of which has been accorded. The parties need not be listed in any specific order. Use a separate form for each count.

(See MPEP 2309.02)

BOARD OF PATENT APPEALS AND INTERFERENCES: An interference is found to exist between the following cases:

This is count 1 of 1 count(s)

1. NAME	SERIAL NO.	FILING DATE	PATENT NO., IF ANY
Heiber et al.	243,415	May 16, 1994	5,516,523

The claims of this party which correspond to this count are:	The claims of this party which do not correspond to this count are:
1-24	NONE

*Accorded benefit of:

COUNTRY	SERIAL NO.	FILING DATE	PATENT NO., IF ANY
USA	027,508	February 22, 1993	5,346,701

2. NAME	SERIAL NO.	FILING DATE	PATENT NO., IF ANY
Scholz et al.	Not yet assigned	May 14, 1997	NONE

The claims of this party which correspond to this count are:	The claims of this party which do not correspond to this count are:
125-144	NONE

*Accorded benefit of:

COUNTRY	SERIAL NO.	FILING DATE	PATENT NO., IF ANY
USA	510,046	May 31, 1995	
USA	842,222	February 26, 1992	
USA	607,863	November 01, 1990	
USA	486,554	February 27, 1990	
USA	431,664	November 03, 1989	

3. NAME	SERIAL NO.	FILING DATE	PATENT NO., IF ANY

The claims of this party which correspond to this count are:	The claims of this party which do not correspond to this count are:

*Accorded benefit of:

COUNTRY	SERIAL NO.	FILING DATE	PATENT NO., IF ANY

If a claim of any party is exactly the same as this count, it should be circled above. If not, type the count in this space (attach additional sheet if necessary):

SEE ATTACHED SHEET

*The serial number and filing date of each application the benefit of which is intended to be accorded must be listed. It is not sufficient to merely list the earlies application necessary for continuity.

DATE	PRIMARY EXAMINER	TELEPHONE NO.	ART UNIT
NOTE: FORWARD ALL FILES INCLUDING THOSE BENEFIT OF WHICH IS BEING ACCORDED.		GROUP DIRECTOR SIGNATURE (if required)	

I:\ADR\19980028PTO850.WPD

PTO-850-(Rev. 09-22-97) (OSMMN version) Count # _____

INTERFERENCE-INITIAL MEMORANDUM

BOARD OF PATENT APPEALS AND INTERFERENCES: An interference is found to exist between the following cases:
This interference involves 2 Parties

EXAMINERS INSTRUCTIONS - This form need not be typewritten. Complete the items below and forward to the Group Clerk with all file including those benefit of which has been accorded. The parties need not be listed in any specific order. Use a separate form of each count.

(See MPEP 2309.02)

BOARD OF PATENT APPEALS AND INTERFERENCES: An interference is found to exist between the following cases:

1. PARTY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
Heiber et al.	243,415	May 16, 1994	5,516,523	May 14, 1996

If application has been patented, have maintenance fees been paid? X Yes No __ Maintenance Fees not due yet ___ __

The claims of this party which correspond to this count are: 1-24
The claims of this party which do not correspond to this count are: None

*Accorded the benefit of:

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
USA	027,508	February 22, 1993	5,346,701	Sep 13, 1994

2. PARTY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
Scholz et al.	08/855,933	May 14, 1997	NONE	

If application has been patented, have maintenance fees been paid? _____Yes _____No Maintenance Fees not due yet

The claims of this party which correspond to this count are: 125-150 (allowable)The claims of this party which do not correspond to this count are: NONE

*Accorded the benefit of:

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
USA	510,046	May 31, 1995	5,750,134	5/12/1998
USA	842,222	February 26, 1992		
USA	607,863	November 01, 1990		
USA	486,554	February 27, 1990		
USA	431,664	November 03, 1989		

CLAIM 1 OF THE COUNT

Claim 1 in the Heiber et al. patent

OR

Claims 125, 132, or 139 in the Scholz et al. patent application.

Claim 1 of the Hieber et al. patent consists of the following:

A method of mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/enhancer/polymer/ layer having one surface in contact with and adhering to the mucosal tissue of the oral cavity and an opposing surface in contact with and adhering to an overlying inert layer said inner layer containing from about two to sixty percent by weight of a bile salt enhancer, five to sixty five percent by weight of a hydrophilic polymer and an effective amount of a macromolecular drug having a molecular weight of at least 500 daltons.

Claims 125, 132, or 139 in the Scholz et al. patent application consist of the following:

125. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to the oral cavity mucosa a system comprising an inner drug/enhancer/polymer layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere

thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer, said inner layer containing an effective amount of a bile salt enhancer, from about 29 to 80% by weight of a hydrophilic polymer, and an effective amount of a macromolecular drug.

132. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/enhancer/polymer/layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer said inner layer containing from 0% to an effective amount by weight of a bile salt enhancer, about 29 to 80% by weight of a hydrophilic polymer, and an effective amount of a macromolecular drug.

139. A method for mucosally administering a macromolecular drug to the oral cavity comprising applying to an oral cavity mucosa a system comprising an inner drug/polymer layer having one surface adapted to contact the mucosal tissue of the oral cavity and adhere thereto when wet and an opposing surface in contact with and adhering to an overlying inert layer, said inner layer containing from about 29 to about 80% of weight of a hydrophilic polymer and an effective amount of a macromolecular drug.

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